

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1092661	(X3) Date Survey Completed 05/14/2026
Name of Provider or Supplier Heag Pain Management Center	Street Address, City, State 1305 West Wendover Avenue, Suite A, Greensboro, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	Off-site revisit survey, June 18, 2026, found the deficiencies cited during the May 14, 2026 on-site survey are corrected and the laboratory is in compliance with 42 CFR Part 493 Requirements for Laboratories.
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of Immunoanalysis reagent package inserts (PIs), review of the Abbott ImmTox analyzer's verification of performance specifications, and interview with the Technical Supervisor (TS) and General Supervisor (GS) on 5/14/26, the laboratory modified manufacturer instructions for specimen handling and failed to establish and verify the altered performance specifications prior to patient testing. Findings: 1. Review of Immunoanalysis reagent PIs for 10 assays performed on the Abbott ImmTox analyzer revealed the following: a. 10 of 10 reagent PIs stated, "samples may be stored at 22-30 degrees Celsius" b. 1 of 10 reagent PIs stated, "A minimum temperature of -20 degrees Celsius is recommended for frozen samples." c. 10 of 10 reagent PIs did not indicate storage temperatures at 2-8 degrees Celsius. d. The PIs</p>

indicated stability at 22-30 degrees Celsius for 3 to 14 days, depending on the assay. 2. Review of the Abbott ImmTox analyzer's verification of performance specifications revealed the absence of specimen stability studies. There was no documentation or data that indicated urine specimens are acceptable for testing when stored at 2-8 degrees Celsius or -20 degrees Celsius for any length of time. Patient testing began on 4/15/26. 3. During an interview at approximately 11:00 a.m., the TS stated patient samples were held up to eight weeks while validation studies were completed for the Abbott ImmTox analyzer. The TS confirmed that samples were stored at 2-8 degrees Celsius or -20 degrees Celsius prior to testing. At approximately 1:15 p.m., the GS confirmed patient testing began on 4/15/26.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:
Based on review of the Abbott ImmTox analyzer's verification of performance specifications, review of maintenance logs, and interview with the Technical Supervisor (TS) and General Supervisor (GS), the Laboratory Director failed to ensure verification procedures sufficiently validated the performance of the modified urine drug screen method utilized by the laboratory. 1. Review of the Abbott ImmTox analyzer's verification of performance specifications did not include stability studies necessary to validate a modification in sample storage for urine drug screens performed on the analyzer. The validation records were reviewed and signed by the LD on 4/3/26. See D5423. 2. Review of the Abbott ImmTox analyzer's maintenance logs revealed the analyzer was in use beginning 4/13/26. 3. During an interview at approximately 11:00 a.m., the TS stated patient samples were held up to eight weeks while validation studies were completed for the Abbott ImmTox analyzer. The TS confirmed that samples were stored at 2-8 degrees Celsius or -20 degrees Celsius prior to testing. At approximately 1:15 p.m., the GS confirmed patient testing began on 4/15/26.